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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,196	04/14/2004	T. Douglas Mast	END5312USNP	5885

27805 7590 06/29/2007
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DAYTON, OH 45401-8801

EXAMINER

PAPAPIETRO, JACQUELINE M

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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06/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/824,196

Applicant(s)

MAST ET AL.

Examiner

Jacqueline Papapietro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2004 and 14 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :04/13/2007, 03/19/2007, 03/16/2007, 02/21/2007, 01/04/2007, 10/27/2006, 07/09/2004.

DETAILED ACTION

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castel (US 5413550) in view of Watkin et al (Non-Patent Literature).

Regarding claims 1 and 3, Castel discloses an ultrasound medical treatment system comprising: a) an ultrasound medical-treatment transducer (unit 2 and element 15); and b) a controller (4) which powers the transducer to deliver ultrasound at an ultrasound acoustic power for or beyond a determined treatment time to thermally ablate patient tissue (column 7 line 66- column 8 line 3), and at or above a determined ultrasound acoustic power for a treatment time to thermally ablate patient tissue (column 9 lines 47-48), wherein the controller determines the treatment time from a function (column 9 lines 29-45). Castel does not disclose determining an in vivo treatment time (or ultrasound acoustic power) from a function of experimentally-determined in vitro treatment time (or ultrasound acoustic power) for the transducer to deliver ultrasound at the ultrasound acoustic power (or for the treatment time) for the in vitro treatment time (or at the in vitro ultrasound acoustic power) to thermally ablate patient tissue in vitro.

Watkin teaches conducting studies on in vitro samples to define suitable exposure parameters for a high intensity focused ultrasound procedure in vivo (abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Castel by using experimentally-determined in vitro treatment times and ultrasound acoustic power for the controller to

determine the in vivo treatment time and ultrasound acoustic power, as taught by Watkin, in order to safely and effectively thermally ablate patient tissue in vivo.

Regarding claims 6 and 8, the claimed methods are anticipated by the normal use of the device as disclosed by Castel in view of Watkin.

Claims 2, 4, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castel in view of Watkin as applied to claims 1 and 3 above, and further in view of Hill et al (Non-Patent Literature).

Regarding claims 2 and 4, Castel in view of Watkin discloses the ultrasound medical treatment systems of claims 1 and 3, but is silent regarding specific equations. Hill teaches theoretical models of the formation of ultrasonic focal lesions in tissue. The theoretical models include equations with the following variables/terms: time, patient tissue density, blood perfusion rate, temperature, and ultrasonic power deposition rate (page 260). Examiner takes the position that the claimed equations are manipulations of well-known equations that would be obvious to one skilled in the art. Therefore, at the time the invention was made it would have been obvious to one of ordinary skill in the art to have modified Castel in view of Watkin by using equations substantially equivalent to the claimed equations for the controller to determine the in vivo treatment time and ultrasound acoustic power, as taught by Hill, in order to effectively ablate the target tissue.

Regarding claims 7 and 9, the claimed methods are anticipated by the normal use of the device as disclosed by Castel in view of Watkin in further view of Hill.

Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castel and further in view of Hill et al and Chavrier et al (Non-Patent Literature)

Regarding claim 5, Castel discloses an ultrasound medical treatment system comprising: a) an ultrasound medical-treatment transducer (transducer unit 2) having an ultrasound emitting area (transducer element 15); and b) a controller (4) having a duty cycle (inherently, column 9 lines 4-6) and powering the transducer to deliver ultrasound at or above an ultrasound acoustic threshold (column 9 lines 16-26) to thermally ablate patient tissue (12), wherein the controller determines the ultrasound acoustic power threshold from an equations (column 9 lines 29-45). Castel does not disclose a specific equation for the calculation of the ultrasound acoustic power.

The Examiner takes the position that at the time the invention was made, one of ordinary skill in the art would have manipulated well-known equations in the field of high intensity focused ultrasound, such as those taught by Hill (as described above) and Chavrier (see section I. Theory, especially the discussion regarding the bioheat transfer equation), in order to determine the ultrasound acoustic power threshold. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Castel in view of Hill and Chavrier by determining the ultrasound acoustic power threshold from an equation substantially equivalent to the claimed equation in order to effectively ablate the target tissue.

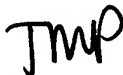
Regarding claim 10, the claimed methods are anticipated by the normal use of the device as disclosed by Castel in view of Hill and Chavrier.

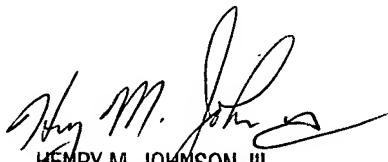
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Papapietro whose telephone number is (571) 272-1546. The examiner can normally be reached on M-F 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jacqueline Papapietro
Art Unit 3739


HENRY M. JOHNSON, III
PRIMARY EXAMINER